UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	MDL No. 1456
THIS DOCUMENT RELATES TO: ALL ACTIONS	CIVIL ACTION: 01-CV-12257-PBS Judge Patti B. Saris

PLAINTIFFS' MEMORANDUM IN RESPONSE TO DEFENDANTS' UNAUTHORIZED POST-HEARING SUBMISSIONS REGARDING THE MEANING OF AWP

In the wake of the summary judgment hearing held on May 23, the Track One Defendants have submitted two briefs: (i) Track 1 Defendants' Notice of Supporting Authority Regarding Congressional Statutory Adoption of AWP in 1997 filed on May 26, 2006 (the "Notice"); and (ii) Track One Defendants' Memorandum Addressing Class Plaintiffs' "Plain Meaning" Argument filed on May 30, 2006 ("Defs. Br."). For the reasons set forth in Plaintiffs' motion, the Court should strike both briefs from the record and refuse to consider them. In the alternative, if the Court accepts these briefs, Plaintiffs request leave for the Court to consider the responsive material contained below.

PLAINTIFFS' INTERPRETATION OF AWP IS CONSISTENT WITH THE PLAIN MEANING RULE AND PROPER AS A MATTER OF LAW

Defendants recycle arguments in support of their bankrupt assertion that Congress did not intend AWP to mean an actual average of wholesaler prices. Defs. Br. at 1. The record demonstrates that Defendants' interpretation is just plain wrong.

A. The Plain Meaning Rule Applies

1. The Plain Meaning Rule is the Default Interpretive Tool

As Defendants painstakingly avoid discussing, the default rule for construing statutory provisions left undefined by Congress is to apply the plain and ordinary meaning of those words using standard English dictionaries. *United States v. Lachman*, 387 F.3d 42, 50-51 (1st Cir. 2004) (quoting *Textron Inc. v. Comm'r*, 336 F.3d 26, 31 (1st Cir. 2003)). Defendants have no answer to this default rule and provided none at oral argument. As Plaintiffs have explained, dictionaries show that "average" has a definite meaning as a mean proportion, and that "wholesale price" refers to the price that a retailer pays in expectation of reselling to its customers at a higher price in order to make a profit. *See* BLACK'S LAW DICTIONARY at 135 and

1597 (6th ed. 1990); AMERICAN HERITAGE DICTIONARY at 144 (2d ed. 1991). Departure from the plain meaning rule is ***rare***: "[C]ourts will only look behind statutory language in the rare case where a literal reading must be shunned because it would produce an absurd outcome." *Textron, Inc. v. Comm'r*, 336 F.3d 26, 31 (1st Cir. 2003) (quoting *Sullivan v. CIA*, 992 F.2d 1249, 1252 (1st Cir. 1993)).

2. Applying the Plain Meaning Rule does not Lead to an Absurd Result and is Consistent with Congress's Intent to Control Medicare Costs

Defendants fail to demonstrate that applying the plain meaning of AWP produces an absurd outcome. Defendants' first "justification" for abandoning the plain meaning rule is to exclaim that Congress could not have intended physicians to be reimbursed at less than their actual costs of acquiring drugs. Defs. Br. at 1-2. ***Yet applying the plain meaning rule does not lead to this result***. As Judge Stearns explained in rejecting this very same defense argument in *In re Lupron Mktg. & Sales Practices Litig.*, 295 F. Supp. 2d 148 (D. Mass. 2003), "by setting the Medicare reimbursement rate below the AWP, Congress took a tentative step towards using Medicare's purchasing power as a means of driving down the cost of prescription drugs to the Medicare program. 'Average,' after all, means that in a competitive market, some prices will be higher and some lower than the median. Congress might reasonably have wished to put Medicare on the lower rung of the equation." *Id.* at 163.

As Judge Stearns also recognized, Congress did not intend Medicare Part B's drug benefit to be a money-making regime for physicians.[1] To the contrary, Congress wanted to

[1] "The suggestion that Congress would deliberately condone a bribery scheme using public funds to enrich drug manufacturers and physicians is, to say the least, unusual. . . . If this were Congress's purpose, one would think it would have been more effective to simply bribe doctors directly without offering drug companies a cut. On the larger issue, I do not understand why a doctor, who is being paid to administer a drug to a patient, is entitled to earn a profit on the drug he injects. A doctor does not earn a commission (or so one hopes) on a drug that he prescribes." *In re Lupron*, 295 F. Supp. 2d at 163 & n.15.

create clear incentives in the Medicare reimbursement regime to have Medicare providers actively seek the lowest cost for the drugs. This interpretation is consistent with other federal drug reimbursement schemes that expressly intend the federal government to pay less than the usual cost for the drug sold, including the 340B program, the Veterans' Administration ("VA") program, and the Medicaid "best price" and rebate regime. In all of these contexts, the government intended to pay less than the market rate. Medicare reimbursement at less than AWP was simply another means of achieving savings, although that pricing mechanism would not yield the same magnitude of savings as, for example, the VA program. Indeed, various sections of Part B, as well as Part A, reveal painstaking efforts by Congress to achieve administratively efficient methods by which to reimburse, but not overpay, providers and suppliers. This context thus reveals the absurdity of Defendants' interpretation of AWP, under which Congress intended to create a system that had no control on expenditures and the money that providers and drug companies could make at the expense of taxpayers.

These observations are wholly sensible and expose a fundamental flaw in Defendants' "sky is falling" tactic. Given the purchasing power of the Medicare program, Congress understood that doctors administering Part B drugs to patients could purchase at a lower cost than physicians who did not treat high volumes of Medicare patients. In fact, the discovery obtained to date demonstrates that doctors who were high volume purchasers received substantial discounts, rebates and other reductions in costs, resulting in purchase prices substantially below AWP. To paraphrase Judge Stearns, Congress might reasonably have expected that, in a competitive market, Medicare providers would be purchasing drugs at prices ***lower*** than the median, and not that they would be purchasing drugs above the median while being reimbursed less. Indeed, Defendants' parade of governmental studies demonstrates that, by January 2004

when the statutory amendment to reimburse drugs at 85% of AWP became effective, Congress recognized that physicians purchasing drugs for infusion under Medicare Part B were receiving substantial discounts. *See also* History of AWP Reimbursement Formula and "Government Knowledge" Chronology, attached as Exhibit 1 hereto.[2]

Yet the existence of these discounts in the marketplace did not necessarily mean that such discounts were universally available or that Congress knew that everyone purchased below AWP. Indeed, the evidence shows otherwise, including Defendants' efforts at concealment.[3] Moreover, Defendants' assertions of Congressional awareness and complicity in their scheme to bribe doctors using public funds are also belied by Congressional action in 2000 recognizing that more studies were needed to determine "the average prices at which . . . drugs . . . are acquired by physicians and other suppliers . . . ." Medicare, Medicaid and SCHIP Benefits Improvement Act of 2000 ("BIPA"), Pub. L. No. 106-554, § 429(c). Thus, in 2000 Congress still did not have a thorough understanding of prevailing drug prices in all distribution channels, even if it was seeing at least some evidence of a downward pricing trend. It is only logical then to conclude that Congress expected Medicare Part B (and the taxpayers) to benefit from this downward trend in prevailing market prices by increasing the discount off of AWP for reimbursement purposes. Of course, this does not mean that Congress believed that AWP was something other than an actual average. Nor does it mean that Congress expected that physicians participating in Medicare Part B would be incurring losses on drugs reimbursed at a discount from an actual average of wholesale prices.

[2] Plaintiffs submitted this chronology to the Court during the May 23rd summary judgment hearing.

[3] *See In re Lupron*, 295 F. Supp. 2d at 168 n.19 ("[I]f everything [about Lupron] was known to everybody, why did [d]efendants emphasize secrecy?"); *see also* Plaintiffs' Memorandum in Opposition to Track 1 Defendants' Joint Motion for Summary Judgment at 24-28 (April 7, 2006).

3. The Absence of Detailed Implementing Regulations Supports Application of the Plain Meaning Rule

Defendants also attempt to justify abandonment of the plain meaning rule by pointing to the "extensive regulations and agency guidance" issued after Congress adopted a "best price" requirement in 1991 for Medicaid and the ASP reimbursement system in 2005 for Medicare Part B, arguing that if Congress had intended the plain meaning rule to apply, "one would have expected a very clear statement to that effect in the statute and comprehensive instructions on how to determine AWP." Defs. Br. at 2-3. But Defendants have it backwards: the plain meaning rule is ***the default*** and has been for decades. When Congress intends something ***other*** than the plain meaning rule to apply, it then provides a different definition. Thus, the lack of Congressional definition, coupled with HCFA's decision not to specify a definition beyond the plain meaning of the phrase in implementing regulations, demonstrates that Congress intended the plain meaning of AWP to apply. Indeed, Defendants' argument proves too much: the very fact that "extensive regulations and agency guidance" were needed to implement the "best price" and ASP regimes, but were ***not*** needed to implement the AWP regime proves "in spades" that the plain meaning of AWP would apply.[4]

B. Defendants Ignore Crucial Interpretive Guidance

Defendants also cite to findings and testimony associated with Congress's statutory adoption of AWP in 1997, Defs. Notice at 1-2 and Defs. Br. at 4-5, yet Defendants omit much

[4] Defendants also present a litany of questions that they claim remain unanswered if the plain meaning of AWP applied, questions that – tellingly – remain unanswered under Defendants' theory of how AWP should be defined. Defs. Br. at 3 n.5. Yet these questions do not make the plain meaning of AWP unworkable. For instance, after passage of the Balanced Budget Act of 1997, HCFA clarified that AWP meant a national average. 63 Fed. Reg. 58814, 58849 (Nov. 2, 1998). Furthermore, questions about whether the AWP should be calculated on a per unit basis versus separately for each NDC, whether rebates should be included and what pricing channels should be included are mere red herrings. ***Notably, none of these purported uncertainties stopped Defendants from reporting to the publishers AWPs by NDC (or list prices from which AWP was formulaically determined)***.

more important – indeed crucial – pieces of interpretatory guidance. First, Defendants overlook the 2003 House Committee on Ways and Means explanation that "AWP is intended to represent the average price used by wholesalers to sell drugs to their customers." H.R. Rep. 108-178(II), 108th Cong. (July 15, 2003) at 197 (Defs. Ex. 82). Second, Thomas A. Scully, former Administrator of the Centers for Medicare & Medicaid Services ("CMS") and now head of PhRMA, testified to Congress that "AWP is intended to represent the average price at which wholesalers sell drugs to their customers, which include physicians and pharmacies."[5] If Congress and CMS had intended AWP to mean something ***other*** than an actual average, the House would not have stated that "AWP is intended to represent the average price," and Administrator Scully would not have endorsed that same interpretation in sworn testimony. Defendants say nothing about these undisputed facts despite Plaintiffs' repeated citations to both the House Report and Scully testimony.

C. Defendants' Interpretation Is Absurd

In light of the foregoing, it is clear that Defendants' proposed interpretation of the meaning of AWP – to wit, whatever Defendants said it meant at any point in time – is truly illogical and leads to an absurd result. If Defendants' jaundiced view of Congressional intent were true, then the same government that Defendants claim knew about and condoned the AWP manipulation schemes would not have criminally prosecuted TAP, AstraZeneca and Bayer. If Defendants' view of Congressional intent was correct, TAP, AstraZeneca, and Bayer would never have paid collectively ***over a billion dollars*** to settle the Department of Justice ("DOJ")

[5] *See* March 14, 2002, Testimony of Thomas A. Scully on Reimbursement & Access to Prescription Drugs under Medicare Part B, Senate Finance Committee, Subcommittee on Health at 5, attached as Exhibit B to the Declaration of Steve W. Berman in Support of Plaintiffs' Motion for Partial Summary Judgment Against All Track 1 Defendants.

allegations of pricing and billing fraud that are nearly identical to those brought by Plaintiffs here.[6] If Defendants' interpretation was correct, the Office of the Inspector General would not have issued, in cooperation with DOJ and CMS, Guidelines that (i) mandated the truthful reporting of pricing information used directly or indirectly in determining Medicare reimbursements and (ii) reminded manufacturers that AWP manipulation was unlawful (and the manufacturers, via their trade association PhRMA, would not have promulgated a voluntary code of compliance essentially adopting the new Guidelines). Moreover, had Congress intended AWP to be fictitious, it would not have investigated Defendants for their Medicare pricing practices.

Defendants' view that the Court must look only to "what was published" and nothing more also leaves a myriad of unanswered questions. If Congress did not intend AWP to be an actual average, then what did Congress really believe AWP to represent? Did Congress truly intend to surrender all control over Medicare fiscal responsibility by tying Medicare reimbursement to a metric that was wholly controlled by the pharmaceutical industry? Did Congress truly intend to have Medicare reimburse drugs at whatever prices Defendants reported to the publishers, even if those prices were 1000% or more above the actual average prices in the marketplace? Is it really reasonable to assume that Congress would choose a published reimbursement benchmark that it knew would not constitute a reliable signal for prices in the marketplace and that, consequently, Congress and taxpayers would willingly pay a "sucker

[6] Defendants also rely on the DOJ submission in *United States v. MacKenzie* kickback case, Defs. Br. at 3, yet that submission is not a substitute for Congressional intent and was submitted by an Assistant U.S. Attorney without authorization to formulate official government policy. *See, e.g.*, *Dantran, Inc. v. United States DOL*, 171 F.3d 58, 67 (1st Cir. 1999) ("[T]he government speaks most authoritatively through its official policymaking machinery, not through individuals, even if individuals occupy responsible agency positions.); *Irving v. United States*, 162 F.3d 154, 166 (1st Cir. 1998) ("To determine what is agency policy, courts customarily defer to the statements of the official policymaker, not others, even though the others may occupy important agency positions. . . . Hence, we decline to accord decretory significance to the area director's or compliance officers' thoughts on OSHA policy requirements. . . ."). In any event, that brief recognized that the government was unaware of both the deep discounts at issue in the case and the defendants' spread marketing.

price"[7] for drugs covered by Part B? For over four years in this litigation, Defendants have failed to answer these critical questions because they cannot without conceding that Congress, if it did not intend the plain meaning of AWP to apply, at least intended the published AWP to have some reasonable proximity to actual costs such that it would serve as a reasonable benchmark for Medicare reimbursement. Plaintiffs have repeatedly challenged Defendants to answer these questions, and Defendants continue to avoid them, with telling effect. Congress did not write the industry a blank check to use (and misuse) Medicare funds.

D. Conclusion

The reasonable interpretation of what Congress has done over the last 15 years is to steadily uncover the truth about Defendants' AWP pricing scheme and then to take action once Congress believed that it had enough information to act. In passing the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (the "MMA"), Congress ultimately recognized that the AWP-based reimbursement system needed substantial reform, which included transitioning away from AWP as a reimbursement metric completely. To be sure, CMS and Congress took a long time to realize the unreliability of the AWP regime, but the intensive period of study begun in the early 2000s in the wake of BIPA ultimately led to the MMA's replacement of the AWP reimbursement benchmark with ASP. The MMA thus represents the culmination of a careful reform effort and not an *ex post* recognition that Congress had always intended AWP to be whatever Defendants wanted it to be. ***Indeed, had Congress always intended AWP to mean whatever was reported by Defendants, the MMA reforms would not have been needed***. The Court should resoundingly reject Defendants' unsupported attempt to avoid application of the plain meaning rule here.

[7] *See In re Lupron*, 295 F. Supp. 2d at 168 n.19.

DATED: June 1, 2006.

By **/s/ Steve W. Berman**

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CERTIFICATE OF SERVICE BY LEXISNEXIS FILE & SERVE
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I, Steve W. Berman, hereby certify that I am one of plaintiffs' attorneys and that, on June 1, 2006, I caused copies of **PLAINTIFFS' MEMORANDUM IN RESPONSE TO DEFENDANTS' UNAUTHORIZED POST-HEARING SUBMISSIONS REGARDING THE MEANING OF AWP** to be served on all counsel of record by causing same to be posted electronically via Lexis-Nexis File & Serve.

/s/ Steve W. Berman
Steve W. Berman

History of AWP Reimbursement Formula and "Government Knowledge" Chronology

	Date	Event
1.	7/31/75	"Actual acquisition cost is difficult to determine...." Acknowledged comments that "actual acquisition cost" be defined as the published AWP. __ Fed. Reg. __, 32293 (Defs. Ex. 3 at 32293).
2.	12/31/80	Comptroller General of the United States reports that "programs using EAC (estimated acquisition cost) established prices that are very similar to the Average Wholesale Price." Report also finds that the 70th percentile of IMS data was equal to AWP. *Programs to Control Prescription Drug Costs Under Medicaid and Medicare Could be Strengthened* (Defs. Ex. 4 at 111).
3.	6/5/91	Proposed HCFA regulation states that "Medicare policy, since the beginning of the Medicare program, has been to base payment for 'incident to' drugs on the estimated acquisition costs." *Medicare Program Fee Schedule for Physician Services*, 56 Fed. Reg. 25,792 (Defs. Ex. 19 at 25).
4.	11/25/91	HCFA sets reimbursement at the "estimated acquisition cost or the national average wholesale price." *Medicare Program Fee Schedule for Physician Services*, 56 Fed. Reg. 59,502, 59, 621 (Nov. 25, 1991) (Defs. Ex. 22). (Prior to this, Medicare paid for drugs based on physicians' estimated costs as measured by the AWP. *MedPac: Report to Congress: Variation and Innovation in Medicare*, Chapter 9 "Medicare payment for outpatient drugs under Part B," June 2003 page 152 (Defs. Ex. 81).
5.	11/6/92	HCFA states that "lack[s] assurance that a substantial number of physicians can obtain drugs at the lowest price available." Appendix III to HHS-OIG Report, *Physicians' Costs for Chemotherapy Drugs* A-02-01049 (Nov. 6, 1992) (Defs. Ex. 26 at 12-13).

	Date	Event
6.	3/15/94	HCFA instructs all Regional Administrators for Medicare how to determine "acquisition cost of drugs" for purposes of reimbursement. Memorandum from Charles Booth Regional Administrators for Medicare (Defs. Ex. 29).
7.	8/94	Medicare instructs carriers to suspend data collection efforts made in response to March 15, 1994 memo pending approval from the Executive Office of Management and Budget to collect the information. Defs. Exs. 30-31.
8.	8/5/97	Congress enacts Public Law No. 105-33 § 4566(a) (codified as 42 U.S.C. § 1395u(o)(1)) and sets reimbursement for certain drugs and biologicals at "95 percent of the average wholesale price." Defs. Ex. 44.
9.	1/1/98	Effective date of amendment of reimbursement formula. Reimbursement for single-source drugs was changed to the lesser of (1) the billed charge on the Medicare claim form or (2) 95% of AWP. 942 U.S.C. § 1395u(o), amended Dec. 8, 2003; 42 C.F.R § 405.517.
10.	11/2/98	After passage of the Balanced Budget Act of 1997, HCFA interprets "Average Wholesale Price" as used in the statute to mean 'the national average wholesale price." 63 Fed. Reg. 58814, 58849 (Nov. 2, 1998).
11.	12/1/98	HCFA directs payors to reimburse physicians 95% of "the AWP as reflected in services such as the Red Book, Blue Book, or Medispan." HCFA Pub. 60 AB, Transmittal No. AB-98-76 (Dec. 1, 1998) (Defs. Ex. 57).
12.	12/21/2000	Congress passes the Medicare, Medicaid and SCHIP Benefits Improvement and Protection Act of 2000 ("BIPA"), Pub. L. No. 106-554, § 429(c), which bars HHS from "directly or indirectly decreas[ing] the rates of reimbursement for Medicare Part B drugs until further studies are done. The legislation directs the GAO to study "the average prices at which...." (Defs. Ex. 70 at § 429(a)).

	Date	Event
13.	1/23/2001	U.S. prosecutes Bayer for marketing spread and Bayer settles.
14.	9/2001	GAO reports that acquisition costs for some drugs range from 13-34 percent off AWP, while acknowledging that determining actual acquisition costs is "complicated" due to the practices of the manufacturer. GAO Report, *Medicare: Payments for Covered Outpatient Drugs Exceed Providers' Cost*, GAO-01-1118 (September 2001) (Defs. Ex. 72).
15.	9/21/2001	In testimony to Congress, CMS Administrator Thomas Scully states that "[t]he AWP is intended to represent the average price at which wholesalers sell drugs to their customers, which include physicians and pharmacies." He also recognized that "Medicare beneficiaries, through their premiums and cost sharing, and U.S. tax payers, are spending far more than the 'average' price that we believe the law intended them to pay." Scully also condemned "situation[s] where a manufacturer can, for certain drugs, arbitrarily increase the reported AWP and, in turn, offer physicians a deeper 'discount,'" and recounted years of effort to lower the benchmark as more studies revealed the existence of marketplace discounts. Scully highlighted Congress's considered decision in the 2000 BIPA legislation that more study of Medicare drug pricing was needed, as well as Congress's direction to the GAO to carry out those studies. Scully even referenced those post-2000 GAO reports. *Medicare Drug Reimbursements: A Broken System for Patients and Taxpayers,* 107th Cong. 87-89 (2001) (Defs. Ex. 73; Plfs. Ex. B).
16.	10/2001	GAO issues Report noting that Congress directed that studies be conducted in response to HCFA steps to lower Medicare drug payments. GAO Report, *Medicare Physician Fee Schedule: Practice Expense Payments to Oncologists Indicate Need for Overall Refinements* GAO-02-53 (Oct. 2001) (Def. Ex. 74).

	Date	Event
17.	10/1/2001	HCFA revises 42 C.F.R § 405.517 to state: "Payment for a drug or biological that is not paid on a cost or prospective payment basis" is "based on the lower of the actual charge on the Medicare claim for benefits or 95 percent of the national average wholesale price of the drug or biological." (Defs. Ex. 71.)
18.	5/5/2003	OIG issues Guidelines developed in consultation with CMS and DOJ and reemphasizing the requisite accuracy of Defendants' price reporting for reimbursement purposes: "Where appropriate, manufacturers' reported prices should accurately take into account price reductions, cash discounts, free goods contingent on a purchase agreement, rebates, up-front payments, coupons, goods in kind, free or reduced-price services, grants, other price concessions or similar benefits offered to some or all purchasers." OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. 23731, 23733-734 (May 5, 2003) (Plfs. Ex. C). The Guidelines also explain that pharmaceutical manufacturers are under a legal duty not to submit "false, fraudulent, or misleading information" where "reimbursement by Medicare and Medicaid…for the manufacturer's product depends, in whole or part, on information generated or reported by the manufacturer, directly or indirectly, and the manufacturer has knowingly …failed to generate or report such information completely and accurately." 68 Fed. Reg. at 23733. The Guidelines also state that it "is illegal to establish or inappropriately maintain a particular AWP if one purpose is to manipulate the 'spread' to induce customers to purchase its product," and that spread marketing is also unlawful. *Id.* at 23737.
19.	6/2003	MedPAC report finds that "the actual price charged to any one customer is a closely guarded trade secret," but that third-party payers were reimbursing for physician-administered drugs on average at 97.5% of AWP with the overall range being 85% to 115% of AWP. *MedPac: Report to Congress: Variation and Innovation in Medicare*, Chapter 9 "Medicare payment for outpatient drugs under Part B," June 2003 page 152 (Defs. Ex. 81)).

	Date	Event
20.	6/20/2003	U.S. prosecutes Astra for marketing the spread.
21.	7/15/2003	The House Committee on Ways and Means acknowledges that "AWP is intended to represent the average price used by wholesalers to sell drugs to their customers." H.R. Rep. 108-178(II), 108th Cong. (July 15, 2003) at 197 (Defs. Ex. 82).
22.	1/1/2004	Effective date of statutory amendment to reimburse drugs at 85% of AWP, although reimbursement for certain specific drugs is particularly described in the applicable regulation.
23.	5/3/2004	U.S. prosecutes Schering and it settles.
24.	1/1/2005	Effective date of Medicare Prescription Drug, Improvement and Modernization Act of 2003 ("MMA") amendments setting reimbursement at "106 percent" of "average sales price" or" wholesale acquisition price" for both single-source and multi-source drugs. (Defs. Ex. 83.)
25.	9/17/2005	U.S. prosecutes GSK for marketing the spread and GSK settles.
26.	3/17/06	U.S. complaint versus Abbott for AWP manipulation.